

**1. Rejection of claims 9-12 under 35 U.S.C. §112, 2<sup>ND</sup> paragraph**

The Official Action states that claims 9-12 have been rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph. In particular, the Official Action states that "in claims 9-10, the term 'reducing' is not clear"; "in claims 11-12, the term 'deprotection' is not clear"; and "in claim 12, the term 'cyclization' is not clear".

**RESPONSE**

Applicants respectfully traverse this rejection. The terms "reducing", "deprotection" and "cyclization" are perfectly clear to a person of ordinary skill in the art in view of the clear use of these terms in the instant specification. As such, claims 9-12 are in full compliance with the requirements of 35 U.S.C. §112, 2<sup>nd</sup> paragraph.

Regarding the rejection of claims 9-10 which contain the term "reducing", applicants respectfully draw the Examiner's attention to the disclosure at pages 17-21 of the instant specification. Page 17 of the specification contains Reaction Scheme 1 which clearly shows a compound of formula 3 being reduced to form a compound of formula 1. The specification at page 17 clearly states that "The compounds of formula 1 can be obtained from corresponding compounds of the formula 3 by methods known to the expert, for example by an asymmetric reduction, which can be performed for example as an asymmetric catalytic reduction." (emphasis added)

The specification then goes on to state at page 18, 1<sup>st</sup> paragraph that "A great variety of catalysts is available for this kind of transformation" and then lists five separate literature references which disclose which catalysts are known by the ordinary skilled artisan to perform such a reduction reaction. The specification then lists at page 18 how those catalysts can be derived by the ordinary skilled artisan from precatalysts. The specification also indicates at page 19 that "[e]ffective asymmetric reduction of prochiral ketones can be achieved using these precatalysts. The optimization of the reaction conditions...and the choice of additives...can be accomplished by the person skilled in the art." (emphasis added)

The specification then states at page 20 that "[f]urther methods to perform the asymmetric reduction mentioned above are known to the expert" (emphasis added) and then gives two further references where such a reaction is described. Then, the specification lists on pages 20-21 no fewer than three alternate methods as to how such a reduction reaction could be carried out by the skilled artisan.

As such, the specification clearly outlines what is meant by the claim term "reducing", so that a person of ordinary skilled in the art would be fully apprised of this claim term's meaning.

Regarding the rejection of claims 11-12 which contain the term "deprotection", applicants respectfully direct the Examiner's

attention to the concept of deprotection contained in the instant specification as the cleaving of a protecting group. Such a use of this term would be understood by a person of ordinary skill in the art. In particular, applicants respectfully draw the Examiner's attention to page 21 of the specification which states that "[c]leavage of the protecting group PG present in the compounds of the formula I can be accomplished using standard methods" and then recites a literature reference which states an exemplary method of carrying out the deprotection of a compound of formula I. Such information, combined with the ordinary meaning of "deprotection" as understood by the skilled artisan, would be sufficiently clear to the ordinary skilled artisan.

As such, the specification clearly outlines what is meant by the claim term "deprotecting", so that a person of ordinary skilled in the art would be fully apprised of this claim term's meaning.

Regarding the rejection of claim 12 which contains the term "cyclization", applicants respectfully draw the Examiner's attention to pages 21-22 of the specification which states that "[t]he cyclization step is carried out under conditions known to the expert" (emphasis added) and then recites a literature reference which exemplifies such a reaction step. The reference to this cyclization step is located directly underneath Scheme 2 which clearly shows a compound of formula 4 undergoing a cyclization reaction wherein a bicyclic compound is converted into a tricyclic

compound (formula 5). Thus, part of the bicyclic moiety is converted (i.e. cyclized) into a third ring.

Such information, combined with the ordinary meaning of "cyclization" as understood by the skilled artisan, would be sufficiently clear to the ordinary skilled artisan. As such, the specification clearly outlines what is meant by the claim term "cyclization", so that a person of ordinary skill in the art would be fully apprised of this claim term's meaning.

Thus, applicants have clearly demonstrated that a person of ordinary skill in the art would be apprised of the definite meanings of the three rejected claim terms upon reading the instant specification and combining it with the common knowledge of the ordinary skilled artisan.

Accordingly, the full scope of the pending claims is clear and definite per 35 U.S.C. §112, 2<sup>nd</sup> paragraph and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

**2. Provisional Rejection of claims 9-12 under 35 U.S.C. §112, 2<sup>ND</sup>**  
**paragraph**

The Official Action states that claims 9-12 are provisionally rejected under the doctrine of obviousness-type double patenting over claim 11 of copending application 10/582,395.

**RESPONSE**

Applicants respectfully traverse this provisional rejection. First, applicants respectfully point out that presently pending claims 9-12 have a different scope than those of the '395 application. In particular, formula (3) of claim 9 differs in scope than the compounds of formula (4) of the '395 application since substituent "PG" cannot be hydrogen in the instant application. Further, applicants respectfully note that the instant application was filed on June 12, 2006, whereas the '395 application was filed June 30, 2006 and has not even been examined yet.

Thus, the instant application was filed before the '395 application and the provisional rejection must be removed if this is the only remaining rejection of the claims. In view of applicants arguments in section 1 outlining how the claims are clear and definite under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, all rejections should be overcome and the presently pending claims are in condition for allowance.

Accordingly, the provisional rejection of claims 9-12 over the '395 application is improper and applicants respectfully request that the Examiner reconsider and withdraw this provisional rejection.

**3. Allowable subject matter**

The Official Action indicates that claims 1-8 are allowable. Applicants thank the Examiner for this indication of allowable subject matter.

**CONCLUSION**

Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw all rejections and allow all pending claims in this application. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if he has any questions or comments.

Respectfully submitted,  
**THE NATH LAW GROUP**

By: 

Gary M. Nath  
Registration No. 26,965  
Sheldon M. McGee  
Registration No. 50,454  
Customer No. 34375

Date: July 12, 2007  
**THE NATH LAW GROUP**  
112 South West Street  
Alexandria, VA 22314  
(703)-548-6284  
GMN/SMM/ROA.doc